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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/763,957

Applicant(s)

BOTELLA MESA ET AL.

Examiner

Maria B. Marvich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

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***Title***

Applicant should avoid the use of novel in the title as patents are presumed to be novel and unobvious.

***Specification***

The disclosure is objected to because of the following informalities: Sequences and references to sequences are listed with references to their identifying <400> numeric indicators. Sequences and references to sequences must be listed by SEQ ID NO: identifiers.

Appropriate correction is required.

This application contains sequence disclosures that are encompassed by the definitions for nucleotides and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Specifically, there are sequences disclosed in Figure 1 and 4 that do not have SEQ ID numbers associated with them.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 15. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Drawings***

Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

### *Claim Objections*

Claims 5, 11-14, 18-21 are objected to under 37 CFR 1.75(c) as being in improper form should refer to other claims in the alternative only and because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 4, 6, 7, 8, 9, 10 and 17 are objected to because of the following informalities: Sequences and references to sequences are listed with references to identifying <400> numeric indicators. They must be listed by SEQ ID NO: identifiers. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Resnick et al. (Medical Sciences, 1993).

Resnick et al. describe on page 4596, 2<sup>nd</sup> column, 2<sup>nd</sup> full paragraph a vector comprised of a sequence of nucleotides defining a promoter driving expression of Platelet-derived growth factor B (PDGF) chain, a promoter that in its native form is inducible in response to shear stress (physical stimulation).

Claims 1-2 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Blume et al. (Plant Journal, 1997).

Blume et al describe a sequence of nucleotides defining a promoter driving expression of the ethylene production gene, ACC oxidase, LEACO1. This promoter in its native form is inducible in response to environmental stress (physical stimulation) (page 738, first column, last

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two sentences through column 2). Promoter deletions are described on page 732, column 2, that are shown to be responsive to stress as 396 and 1825 base pair fragments (page 738, column 2, lines 2-8). As a "portion" can comprise a single nucleotide, the promoter described by Blume et al. can be classified as modular.

Claims 1-3 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodman et al. (WO 98/08449).

Goodman et al. teach a promoter driving expression of the ethylene production gene, ACC synthase (page 2, line 7-10). This promoter is an ethylene inducible promoter and drives transcription in response to ethylene or an equivalent compound (page 8, line 4-7). 5' deletion mutations were generated to determine which portions of the promoter are responsible for expression (page 31, line 24-page 32, line 6). As a "portion" can comprise a single nucleotide, the promoter described by Goodman et al. can be classified as modular.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, 7, 10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 4, 6, 10 and 17 is a relative term that renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term “substantially” is a relative one not defined by the claim, no single set of conditions is recognized by the art as being “substantial” and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

Claims 4, 6, 7, 10 are indefinite in the recitation of “low stringency conditions” and “hybridizes to” because the metes and bounds of the claimed conditions are ambiguous and are not specific. In turn, the metes and bounds of the claimed nucleotide sequences are not defined.

The term “a gene associated with” ethylene biosynthesis in claim 2 and 15 is a relative term that renders the claim indefinite. The term “associated with” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term “associated with” is a relative one not defined by the claim, no single set of conditions is recognized by the art as being “associated with” and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-4, 6-8, 10 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants claim a genus of promoters and modular promoters or a derivative or a homologue thereof that directs expression of genes associated with ethylene biosynthesis such as ACC. Applicants claim a genus of promoters that have at least 25% similarity thereto or a nucleotide sequence capable of hybridizing to SEQ ID NO: 3.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants only disclose the inducible promoter that drives expression of ACC synthase and a modular promoter in which at least a part is responsible for driving expression of ACC synthase. Also disclosed are 7 deletion fragments of pGEL1 that were used to analyze the activity of the promoter and could be considered derivatives of the ACC promoter but these promoters once deleted are of varying activity when in their "native form". Given the diversity of ethylene biosynthesis genes promoters and derivatives and homologues of said promoters and the uncertainty of the activity of any derivative or homologue of said promoter to be effective in driving gene expression, it must be considered that any promoter derivative or homologue must

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be empirically determined. By claiming sequences hybridizable under low stringency conditions, the relationship between the structure of the sequence and its function becomes unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus. In the instant case, applicants only disclose the inducible promoter that drives expression of ACC synthase and a modular promoter in which at least a part is responsible for driving expression of ACC synthase. Given the diversity of sequences that are should be related by at least 25% or 50% similarity to SEQ ID NO:3 and the uncertainty that a sequence related by 25% or 50% similarity will be effective at driving gene expression of a given gene, it must be considered that any promoter derivative or homologue must be empirically determined. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for



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the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kay Pinkney, whose telephone number is (703) 305-3553.



Maria B Marvich, PhD  
Examiner  
Art Unit 1636

October 1, 2002

DAVID GUZO  
PRIMARY EXAMINER  
